UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **September 10, 2015**

PLURISTEM THERAPEUTICS INC.
(Exact Name of Registrant as Specified in Its Charter)

Nevada
(State or Other Jurisdiction of Incorporation)

001-31392	**98-0351734**
(Commission File Number)	(IRS Employer Identification No.)
MATAM Advanced Technology Park **Building No. 5** **Haifa, Israel**	**31905**
(Address of Principal Executive Offices)	(Zip Code)

011 972 74 7108607
(Registrant's Telephone Number, Including Area Code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

On September 10, 2015, the registrant issued a press release describing corporate and financial highlights for fiscal year 2015. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Warning Concerning Forward Looking Statements

Exhibit 99.1 to this Current Report on Form 8-K contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, we are using forward-looking statements when we discuss PLX-PAD's potential to enter the European market in 2018 with conditional approval to treat a type of CLI, when we discuss our preparation for submission of an Investigational New Drug application to FDA for PLX-R18 in the treatment of incomplete hematopoietic recovery following hematopoietic cell transplant, when we discuss PLX-R18's potential to improve the outcome of bone marrow transplantation, and when we discuss our expectation that our current cash and cash equivalents, bank deposits, restricted deposits and marketable securities will support its activities for the next two years. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real surgical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 – Press release of Pluristem Therapeutics Inc. dated September 10, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PLURISTEM THERAPEUTICS INC.

Date: September 10, 2015

By: /s/ Yaky Yanay
Name: Yaky Yanay
Title: President, Chief Financial Officer,
Chief Operating Officer and Secretary

Exhibit 99.1

Pluristem provides Corporate and Financial Highlights for Fiscal Year 2015

HAIFA, ISRAEL, September 10, 2015 --Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, reported yesterday financial results for its fiscal year ended June 30, 2015, and provides corporate and financial highlights for fiscal year 2015.

"During fiscal 2015 we executed our strategy to shorten the time to commercialization for PLX-PAD, our lead product, and significantly advanced the development of PLX-R18, our second product," said Zami Aberman, Pluristem's Chairman and CEO.

"We achieved a major milestone when our clinical development program for PLX-PAD in critical limb ischemia (CLI) was selected for Europe's Adaptive Pathways pilot project. Only a handful of programs were chosen worldwide. Pending a single successful Phase II trial, PLX-PAD could enter the European market in 2018 with conditional approval to treat a type of CLI. Another important milestone was safety clearance of PLX-PAD cells for use in clinical trials in Japan."

"We also advanced our U.S. program for PLX-R18 in the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation. This year we also announced an important new clinical finding from our Phase I/II trial in muscle injury, suggesting that treatment with PLX-PAD could also significantly strengthen muscle force in the contralateral leg.

"During fiscal 2015, we strengthened our valued partnerships with United Therapeutics, Cha Bio and the U.S. National Institutes of Health, and finished the fiscal year with a robust balance sheet. We look forward to a very productive fiscal 2016 on all fronts," Mr. Aberman concluded.

Clinical and Corporate Highlights for Fiscal Year 2015 Include:

- Selection of clinical development program in CLI for the European Medicines Agency's Adaptive Pathways project. Pluristem is receiving in-depth guidance from European regulatory officials as it prepares to submit a Phase II protocol. Positive results from a single Phase II trial may be sufficient for conditional approval to market PLX cells in the EU for a subset of CLI.

- Achieved significant progress towards entry into Japan's Accelerated Pathway for Regenerative Medicine, with the granting of safety clearance for the use of PLX-PAD in Japanese clinical trials, and Japan's agreement to the proposed quality and large-scale manufacturing methods for PLX-PAD.

- Reported an additional significant clinical finding from our Phase I/II trial in muscle injury after total hip arthroplasty. The non-injured gluteal muscle of patients treated with our cells were approximately 40 times stronger six months after surgery than the same muscle in patients who received a placebo.

- Opened 15 additional trial sites and continued patient recruitment in the U.S., Germany, Israel and South Korea for a Phase II trial in intermittent claudication, with a total of 100 patients already recruited.

- United Therapeutics continued recruiting patients for a Phase I trial in pulmonary arterial hypertension.

- Completed successful meetings with the FDA in preparation for submission of an Investigational New Drug application to FDA for PLX-R18 in the treatment of incomplete hematopoietic recovery following hematopoietic cell transplant.

- Reported significant research findings for PLX-R18, including both positive results from the U.S. National Institutes of Health's second trial of PLX-R18 cells for the treatment of acute radiation syndrome and positive findings from a trial completed at Hadassah Medical Center, showing that PLX-R18 could improve the outcome of bone marrow transplantation.

- Strengthen our intellectual property position with 13 new granted patents that cover core technologies for 3D Cell expansion and use of PLX cells in a broad range of indications worldwide. Total of 45 issued patents.

Financial Updates:

During fiscal 2015, Pluristem raised net cash of $17.2 million from issuance of common stock, and from exercises of outstanding warrants and options. The fundraise marked the accomplishment of a goal to increase US institutional ownership. In addition, the Company was awarded $2.9 million grant from the Office of the Chief Scientist (OCS) of Israel's Ministry of Economy to support R&D programs, as well as a "Smart Money" grant from Israel's Ministry of the Economy to support marketing activities in Japan. As of June 30, 2015, Pluristem had $53.1 million in cash and cash equivalents, bank deposits, restricted deposits and marketable securities. The Company expects this will support its activities for the next two years.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells. The cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring no tissue matching prior to administration.

Pluristem has a strong intellectual property position; Company-owned, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement

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